FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

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MEETING

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TUESDAY,
SEPTEMBER 27, 2005

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The meeting convened in Whetstone Room of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, 20877, at 9:03 a.m., pursuant to notice, Carolyn B. Hendricks, M.D., Chair, presiding.

COMMITTEE MEMBERS PRESENT:

CAROLYN B. HENDRICKS, M.D., Chair
CHARLES FINDER, M.D., Executive Secretary
SCOTT FERGUSON, M.D., Member
ALISA GILBERT, Member
JACQUELIN S. HOLLAND, R.N., C.R., Member
MILES G. HARRISON, JR., M.D., Member
CAROL J. MOUNT, R.T. (R)(M), Member
DEBRA L. MONTICCIOLO, M.D., Member
MELISSA C. MARTIN, M.S., Member
LINDA S. PURA, R.N., M.P.A., Member
WILLIAM A. PASSETTI, B.S., A.A., Member
DIANE I. RINELLA, RT (R)(M), Member
JANE B. SEGELKEN, B.S., M.A., Member
MARK B. WILLIAMS, Ph.D., Member

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(9:03 a.m.)

CHAIR HENDRICKS: On the record. I'd like to call this National Mammography Quality Assurance Advisory Committee meeting to order. My name is Carolyn Hendricks and I'll be chairing this meeting with assistance from Dr. Charles Finder to my right who is the Executive Secretary of the National Mammography Quality Assurance Advisory Committee.

I note for the record that the voting members present constitute a quorum as required by 21 CFR Part 14. We also have Dr. Miles Harrison participating in this Advisory Committee via telephone and he had some difficulty yesterday hearing the speakers particularly the speakers from the audience. So I'm going to ask again if individuals participating at the podium to please state clearly your first and last name and your affiliation.

Now Dr. Finder is going to review again the Conflict of Interest Statement for the

participants.

EXEC. SECRETARY FINDER: The following announcement addresses conflict of interest issues associated with this meeting and is made a part of the record to preclude even the appearance of any impropriety. To determine if any conflict existed, the Agency reviewed the submitted agenda and all financial interests reported by the Committee participants.

The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interest. However, the Agency has determined that participation of certain members the need for whose services outweighs the potential conflict of interest involved is in the best interest of the government.

Therefore, waivers permitting full participation in general matters that come before the Committee have been granted for certain participants because of their financial involvement with facilities that will be subject to FDA's

regulation on mammography quality standards with accrediting, certifying or inspecting bodies, with manufacturers of mammography equipment or with their professional affiliation since these organizations could be affected by the Committee's deliberations. These individuals are Ms. Diane Rinella, Ms. Jacquelin Holland, Dr. Debra Monticciolo, Mr. William Passetti, Dr. Mark Williams and Ms. Jane Segelken.

Waivers are currently on file for Dr. Carolyn Hendricks, Dr. Scott Ferguson, Ms. Carol Mount, Ms. Alisa Gilbert, Dr. Miles Harrison, Ms. Linda Pura and Ms. Melissa Martin. Copies of the waivers may be obtained from the Agency's Freedom of Information Office, Room 12A-15 of the Parklawn Building.

We would like to note for the record that if any discussion of state certifying bodies was to take place in any meetings of the Committee it would be a general discussion only. No vote would be taken and no consensus sought. In the interest of getting as many viewpoints as possible,

all SGEs including state employees would be allowed to participate in the general discussion so that all viewpoints could be heard.

In the event that the discussions involve any other matters not already on the agenda in which an FDA participant has financial interest, the participant should excuse himself or herself from such involvement and the exclusion will be noted for the record. With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with accreditation bodies, state doing mammography, inspections under contract to FDA, certifying bodies, mobile units, breast implant imaging, consumer complaints and mammography equipment.

CHAIR HENDRICKS: Thank you. Again at this time, I would like the members of the panel to reintroduce themselves for the record and for the audience.

MEMBER PURA: Linda Pura, Clinical

Coordinator, Los Angeles County Regional Cancer Detection Program.

MEMBER HOLLAND:: Jacquelin Holland, Program Director - Diversity Enhancement, James Cancer Hospital and Soloff Research Institute, Columbus, Ohio.

MEMBER GILBERT: Alisa Gilbert, Office of Native Cancer Survivorship, Anchorage, Alaska.

MEMBER WILLIAMS: Mark Williams, Associate Professor of Radiology, Biomedical Engineering and Physics, University of Virginia.

MEMBER SEGELKEN: Jane Segelken, Breast Cancer Survivor, Ithaca, New York.

MEMBER MONTICCIOLO: Debra Monticciolo, Professor of Radiology and Section Chief of Breast Imaging at Texas A&M.

MEMBER FERGUSON: Scott Ferguson, Diagnostic Radiologist from West Memphis, Arkansas.

MEMBER RINELLA: Diane Rinella. I'm a Mammography Technologist and Consultant from California.

EXEC. SECRETARY FINDER: Dr. Charles

Finder. I'm the Executive Secretary of this Committee.

CHAIR HENDRICKS: Carolyn Hendricks. I'm a Medical Oncologist practicing in Bethesda, Maryland.

MEMBER PASSETTI: Bill Passetti. I'm the Director of Florida's Radiation Control Agency.

MEMBER MOUNT: Carol Mount, Manager of Breast Imaging and Intervention, Mayo Clinic, Rochester, Minnesota.

MEMBER MARTIN: Melissa Martin. I'm an Consulting Medical Physicist in Southern California.

CHAIR HENDRICKS: Dr. Harrison.

MEMBER HARRISON: Miles Harrison, Breast Cancer Surgeon, Sinai Hospital, Baltimore.

CHAIR HENDRICKS: Thank you very much. As the last item of Committee business before we begin the meeting, I would like to read a brief statement addressed at the individuals in the audience who make a public statement today.

Both the Food and Drug Administration and the public believe in a transparent process for

information-gathering and decision-making. To ensure such transparency at this open public hearing session of the Advisory Committee, the FDA believes that it is important to understand the context of an individual's presentation.

For this reason, the FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise this committee of any financial relationship that you may have with the sponsor, its product and if known, its direct competitors. For example, this financial information may include the sponsor's payment of your travel, lodging or other expenses in connection with your attendance at this meeting.

Likewise, the FDA encourages you at the beginning of your statement to advise this committee if you do not have any such financial relationship. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

Now we'll move into the open public hearing portion of this meeting by inviting to the

podium Judith Wagner who is going to speak on Interventional Mammography Regulation. Ms. Wagner. The speakers will be confined to ten minutes.

EXEC. SECRETARY FINDER: Before you start, I just want to make mention. We no longer have our timer. So I'm going to have to motion to you. If I start making signals.

MS. WAGNER: Welcome. Thank you. Thank you all for having me speak today. As a nurse, breast cancer advocate and breast cancer survivor.

My advocacy for quality breast care began two years ago when suspicious lesions were found on my yearly screening mammogram and a stereotactic biopsy was attempted by a surgeon who could not localize my lesion and perform the biopsy. so I went to an accredited breast center where a diagnostic radiologist localized my calcifications without difficulty, performed the biopsy and I was diagnosed with low-grade DCIS (Ductal Carcinoma In Situ).

This began my quest of knowledge regarding the standards necessary to perform image-

guided breast biopsies. Why did the hospital that I had worked in for 20 years and trusted not have an expert in imaging doing my stereotactic breast biopsy? As a nurse, I was really unaware of the standards. I had worked 20 years in the ICU and went about life and didn't really realize what the standards were for performing these image-guided breast biopsies. And after I found out, I wanted other women to know what I didn't know before they had this experience.

So I went the process of my DCIS treatment and I gathered information. I had hundreds of articles from the internet. I contacted my senators, my congressmen, Senator Mikulski, the FDA, the ACR, Tommy Thompson who was at that time Health and Human Services Secretary and I built my knowledge base because this was going to be the biggest advocacy of my nursing career.

I actually last week presented my talk. I have a PowerPoint presentation called "Choosing Wisely: How to Make Informed Breast Biopsy Decisions" at the Milwaukee Athletic Club and I was

sitting with one of the board members who said, "And how do you get paid? Are you paid for doing this?" I said, "No, this is my mission in life. This is my mission to let women know before they get into this position where someone says you have a lesion or a suspicious mammogram and they go ballistic because I was that woman. I wanted an answer yesterday." Even though I felt I was a very strong woman, you hear that, and I think many of you know, you just short circuit.

So I began writing articles in national magazines, nursing publications, one called "Nursingmatters" and I received calls from Parish Nurses who read "Nursingmatters" to speak at churches and I speak where anyone will listen. I've appeared on a local NBC affiliate in my area regarding my advocacy of quality breast centers and accredited breast centers and women contacted me regularly about questions and concerns that they have about their breast biopsy decisions. I correspond with nurses in hospitals throughout the country who have issues of concern related to the

quality and performance of breast biopsy and the standards of practice for physicians who perform them.

I believe that early diagnosis of breast cancer when it is less that 15 mm is critical for improvement in breast cancer mortality and morbidity and that quality standards must be mandated for performance in all these areas of mammography from screening to diagnosis, biopsy and treatment. Women need to be able to trust the medical system. I trusted a system that I worked in 20 years and they need to be assured that this physician who performs these procedures maintains the high quality standards.

So I speak as I say wherever I'm invited and I have a handout called "Key Questions That Determine a Quality Breast Center" and I give it to women and I make them think.

I have spoken before the IOM Committee, Improving Mammography Quality Standards in September 2004 and I requested that all image-guided breast biopsies, stereotactic, ultrasound and MRI be

required to have mandated accreditation. This request was discussed by the committee and it was stated that the name MQSA would need to be changed in order to include non-mammographic imaging modalities. My request was, "Then change the name."

When the study did come out, it was titled "Improving Breast Imaging Quality Standards" because breast care has evolved. The umbrella has gotten bigger. We need to include everything underneath it in the diagnostic process of breast care.

I found a very important statement in the IOM Study of 1999 and I use this at all my presentations. It's right up on my slide. "These studies identify multiple steps during the diagnostic evaluation of breast cancer at which the quality of care may be affected by the quality of the procedure. Poor quality at any step could significantly impact the overall quality of the care provided." About two weeks ago, I had the privilege to spend time in London with Dr. Nicolas Perry who is the Consultant Radiologist and Head of

Mammography at St. Bartholomew's in London. He echoed the same sentiment in this statement. He said, "I believe that quality is more than just a word and a chain is no stronger than its weakest link." In fact, in London, they are going to be doing the fourth edition of their European Guidelines for Mammography and he was requested by the European Parliament to incorporate more on the diagnostic portion of it and the physicians who perform it. So that will be coming out in October of this year. He will be presenting it before the European Parliament.

I believe that the Diagnostic Radiologist should be the sub specialist dedicating 100 percent of his time to breast imaging in order to perform quality care. I have found in all my studies that the majority of radiology groups do not have radiologists who perform breast care 100 percent because they still have to take call and weekends and because of the financial impact of not getting enough for mammography, they can't afford to raise this area of radiology to the level that it

deserves.

And there's a recent article by Jerry Kolb the National Consortium of Breast Centers, it's called the "Bulletin," and it's entitled "Good Enough - The Enemy of Great."

I have been in communication with numerous breast care leaders in this country and keep echoing to me the same concerns: medical legal issues, inability to fill Breast Fellowship positions; and cost of proposed auditing if the IOM Study Recommendations would be accepted. So I speak out for quality being mandated and yet I realize none of this can happen unless reimbursement for mammography and the above concerns are put into place before the recommendations are mandated. There needs to be increases in reimbursement for mammography and biopsy procedures before these recommended mandates can be put into place.

How are we going to get new fellowship positions filled when radiologists are unhappy because they have to do mammography? I know that screening mammography saves lives for women, wives

and mothers and if you ask Tommy Thompson, daughters because his 33-year-old daughter was diagnosed last year with breast cancer. Dr. Daniel Kopans in a recent cover story, "MQSA Historic Success Becomes Regulatory Threat," Diagnostic Imaging, September 2005 stated, "Mammography is difficult, stressful work but since screening began, the breast cancer death rate in the U.S. has dropped by 25%. Better therapies have also contributed, but the majority of that decrease is from screening." And I am one of those people who had good screening and they found my micro calcifications.

That is why I believe that mammography deserves to be a sub specialty of radiology and radiology groups should give it the same reverence that they do MRI, Interventional Radiology because after all, isn't mammography important? You all have mothers and daughters and wives. After all, we are also looking at these costs and by the 2010, and this is in an article by Dr. William Eckland, 50% of all women in this country will be mammography eligible. The baby boomers are coming. I'm the

first.

If mammography is not made a sub specialty and radiologists are forced by their groups to read the 480 mammograms per year often without a committed desire how will medical students and residents ever learn this broad scope of breast care? That's what Dr. Perry says. It's a broad scope.

I would request, I hope and desire, that this committee will take the necessary steps to insure that the recommendations of the IOM Study are adopted by both the FDA and Congress so that women throughout this country will receive their breast care, including screening, diagnostic, image-guided biopsies performed by dedicated Accredited Imagining Physicians who practice breast care with the highest of standards mandated under the BIQSA (Breast Imaging Quality Standards Act). And we need to have centers of excellence so that this can be performed.

I would also request that the committee and Congress address the costs of implementing these proposed recommendations so that mammography will

not lose physicians and centers due to the increased cost incurred due to the mandating of improved standards of care. The burden of increasing mandates on an already low-reimbursed procedure will put further stress on radiology groups and all facets of mammography. Thank you.

CHAIR HENDRICKS: Thank you very much. Any comments on the presentation from the audience or the panel? Then we move to Dr. Richard Wagner who is going to speak on interventional mammography regulation.

DR. WAGNER: Thank you for giving me the opportunity to present my statements in person to this advisory committee. I have no conflict of interest.

My name is Richard Wagner. I have been a general radiologist in private practice in the Milwaukee area for almost 27 years. I have performed almost all aspects of general radiology including CT, MRI, ultrasound, nuclear medicine, many interventional procedures and mammography including screening and diagnostic.

After 25 years, I was removed from my sites of practice after raising quality of practice issues having to do with nonradiologists performing poorly interventional breast procedures. This initially began after my wife developed suspicious calcifications on her screening mammogram. A non-radiologist attempted a stereotactic biopsy but could not find the calcifications. This prompted taking my wife to an accredited breast center where a dedicated breast radiologist easily found the calcifications which were biopsied and DCIS was diagnosed.

This made me question why there was a difference in her experience and treatment between the two facilities. I began to discover that there were too many poorly performed biopsies including image-guided as well as open surgical. Also, because of poor concordance, there were delays in diagnosis. There were more than 50% open biopsies being performed. Patients were not informed of their biopsy options. I also questioned whether the hospital's credentialing and re-credentialing

standards regarding breast biopsies were being met.

I brought these issues to the Quality Assurance Committee with no substantive action. Meanwhile, I regularly began speaking to patients regarding alternatives to open biopsies. This further angered my non-radiology colleagues. Initially I was verbally harassed. Ultimately economic pressure was applied to my group. If they would not remove me from my sites of practice where I had spent my entire professional career, the clinic contract would not be renewed. I was moved to other sites that my group covered.

The contract was recently renewed but not before two other partners were also removed from the clinic for also raising quality issues and speaking to the patients. Recently in on of our ACR stereotactic and ultrasound accredited sites, a different group of non-radiologists is pressuring administration into performing stereotactic biopsies by threatening to move their breast patients to another facility. It appears at this time that they will succeed which would put this site at risk for

losing its accreditation. Again, economic pressures succeed at the expense of quality.

I have spent the last year working in friendlier venues within my group. I have developed a passion for performing quality breast care. I have dedicated a large portion of my time, including vacation, educating myself in breast care. This includes reading, breast conferences and mini fellowships. I recently submitted my resignation to my group and plan to spend the remainder of my career as a dedicated breast radiologist.

There are significant differences in the practice environment of radiologists performing breast care in private practice versus those in academic settings and certain multi-specialty practices. A major negative difference is the turf issue which unfortunately is frequently economically driven. Many image-guided breast procedures are performed by highly skilled, qualified, and dedicated physicians but all too frequently many are performed by less-qualified physicians who have control of the patient and/or the equipment to

perform these procedures.

This problem could be resolved by implementing mandated accreditation standards for all image-guided breast biopsy procedures thus resulting in the highest of standards being met by any physician performing these procedures. This would require uniform accreditation and changing MQSA to BIQSA (Breast Imaging Quality Standards Act) so that all image-guided breast biopsies would be included.

Currently there are a multitude of credentialing bodies with varying standards. It is natural that the least qualified providers will seek credentialing with the organization for which they can meet their standards. Mandating one high quality standard for all physicians to achieve will improve quality and outcomes and decrease costs.

The patient is unaware that there are different credentialing standards and is often not informed. This would also eliminate the turf issues which often lead to a very unpleasant practice environment for a significant number of physicians

who would prefer to deliver quality breast care without having to deal with often hostile professional relationships due to these turf issues. These issues also contribute to recruitment problems and veteran providers abandoning breast care.

It has become increasingly evident since I have become an advocate for quality breast care that voluntary methods for accreditation are not working. These are providers that comply with the recommended standards, but unfortunately a large number do not. These are the providers who could not meet these standards if they were mandated. I strongly believe that if mandated standards of accreditation for all aspects of breast care were implemented there would be a greater interest in practicing this specialty by physicians who are truly dedicated and would provide high quality-high volume service.

Conversely, the radiologists who are disinterested in breast care but are forced by their group to do breast care would be weeded out, very

often to the benefit for the women who are not aware of the current vast differences in breast care standards and the level of competence and degree of interest of their providers. More physicians would probably be inclined to enter the specialty of breast care if it was a sub specialty that received the respect it deserved for decreasing the mortality of breast cancer.

It is discouraging to practice in an environment where quality is superseded by economic incentives when non-specialized practitioners "skim the gravy" but refer the difficult cases to those who have greater proficiency and expertise in the performance of these more difficult image-guided procedures. There is a fear that if accreditation standards were raised and mandated, there would become a shortage of breast care providers.

I believe that this would be a short-term effect at worst. It would discourage and ultimately eliminate physicians with little "true" interest in breast care. The remaining providers would be truly qualified as well as interested in

providing high quality breast care. This would become a "respected specialty," not the poor orphan that it is now. High quality providers would result in lower incidence of malpractice.

However this issue should also be addressed via tort reform. Reimbursement issues need to be addressed. This is a real concern for a large number of breast care specialists who are in favor of the proposed reforms but are very concerned about the costs of their implementation. To mandate recommendations without a plan to finance them is a setup for failure.

As addressed in the recent IOM Study, "Improving Breast Imaging Quality Standards," there is a need to recruit new physicians into breast care. However these new physicians need protection from the various negative factors which are currently preventing recruitment and causing practicing providers to quit in frustration. These factors are turf issues, low reimbursement and malpractice concerns.

The principal goal of screening

mammography is to decrease the mortality and morbidity of breast cancer. This has been shown to have an effect when cancers are detected when they are small and have not had a chance to metastasize. At this early stage, they are curable and, from an economic standpoint, early stage cancers are much less costly to treat than more advanced cancers. Unless cancers are found in an early stage when they are small, there is little improvement in mortality over those that are found clinically.

Current treatments have had little effect on improving survival for later stage cancers. From a screening standpoint, missing the small cancers and only finding the larger cancers defeats the purpose of screening and is wasted money.

To achieve this goal of early detection, there is a need for highly trained, dedicated breast imaging specialists who have high quality screening skills who regularly find these early cancers and are capable of performing the image-guided, minimally invasive biopsies that are often required

for diagnosis and treatment planning. These image-guided procedures require imaging equipment that is user-dependent.

Too many biopsies are performed without the knowledge of the proper indications of these image-guided procedures and are often economically driven. All too many biopsies are performed in private offices where the quality of the imaging equipment is suboptimal, high standards of practice and proper documentation of the procedures are not performed, and individual performance standards are not monitored nor are they currently required.

In summary, the patients and dedicated breast care providers need protection which would be provided by mandatory accreditation of all aspects of breast care. There needs to be improvement in reimbursement for breast care. Why is breast care less valued than other aspects of medicine, yet it is the most regulated? This regulation is expensive and is the responsibility of the provider. There needs to be malpractice reform particularly relating to breast care.

These issues are of major concern for people who are currently in breast care. They are deterrents for future breast care providers and must be addressed if quality breast care can continue and hopefully expand its scope. Thank you for allowing me to present my views during this important era in improving breast care.

CHAIR HENDRICKS: Thank you very much. Any questions from the panel or the audience regarding the presentation? Then at this time, Dr. Finder's going to read some written comments submitted by Dr. Murray Reicher on "Full Field Digital Mammography Guidance."

EXEC. SECRETARY FINDER: These comments will basically apply to our discussion later on today when we discuss our various guidance documents. But the following comment was received from Dr. Murray Reicher who is Chairman of DR Systems, an RIS and PACS vendor. So that's his conflict of interest acknowledgment.

His specific input is as follows: Page 15, question 5 of the Guidance document which

everybody should have in the handouts and again we'll go over it in detail in the afternoon section. This section refers to the labeling of images at the time of presentation and I agree with the comments. You may be aware that FFDM Manufacturers deal with the issue of labeling of laterality and view in various ways. One vendor I know of burns left and right and view markers such as LCC in the FFDM image just as if the technologist used the lead marker with film.

Another vendor does not but only provides the information necessary for a third party viewer to derive that data in the DICOM header field. Another vendor doesn't provide the view dated in standard DICOM field but instead it seems to provide this information in a private tag. I suggest that FFDM Manufacturers should be encouraged to follow one manufacturer's lead and actually embed the laterality and view label in the image pixel since this eliminates the chance of mislabeling by other viewers down the line.

Next comment refers to page 26, question

2. The answer seems to open the door for users to try less than five megapixel monitors although not explicitly stated. My opinion is that readers should have the discretion to pick the monitor they desire as long as there is some instruction or method that encourages display of every pixel so that subsampled viewing of pixels in not-routinely performed inadvertently. That's what it says.

My concern is as I have expressed it before is that current mammography's soft copy viewing systems make it easy for viewers to inadvertently subsample pixels when displaying images such as when a four-to-one format is used without understanding what they are doing. I would suggest that you consider the following comments in preparing future guidance documents.

With regard to all imaging, but mammography, the PACS vendor's responsibility with regard to data compression is to provide labeling. But readers can select to perform the primary reading of exams CT, MRI with lossy data compression. This is becoming a very common

practice and is supported by medical literature. There is clearly a difference between lossy data compression and perceptible visually destructive data compression. A computerized radiography image or CT image with a JPEG five-to-one is lossy compressed but not distinguishable from the original by human observers.

With regard to data compression, the Office of Device Evaluation holds device manufacturers to a different standard when it comes to mammography and I don't fully understand what the scientific or legal basis for this different approach is. With mammography, manufacturers are required to label any lossy compressed image not for primary reading or at least DR Systems does that based on our understanding of what we were required to do by the Office of Device Evaluation and MQSA.

If this different approach comes from MQSA and not ODE, your input would be important. If it's coming strictly from ODE, does that mean that if ODE approves a display device that uses lossy compression data for primary mammography reading,

then MQSA policy with regard to that practice immediately changes de factum?

Our pilot research seems to indicate that we can compress GE FFDM mammograms down to three to four hundred kilobytes per image and Lorad/Fischer mammograms down to under one megabyte per image without resulting in visually detectable change in the image and perhaps more before we could alter an ROC curve. That's a big benefit for any mammography provider with multiple sites seeking to improve their mammography by centralizing reading to a single site where an expert mammographer interprets the exams. As you know, data shows that experts may detect the breast cancer with twice the frequency far more as compared with general radiologists readers.

The same logic applies to need for guidance with regard to digitization of all film screen mammograms with discard of the original. This current guidance makes it clear that a facility may elect to digitize prior film mammograms for comparison purposes. We want to go to the next step

and allow a facility with proper quality controls to digitize the prior film and discard the original or give it to the patient. Our belief is that this will not only lower cost but actually enhance safe storage in electronic clinical access for future comparison.

In summary, my questions with regard to both digitizing films and data compression may be condensed into one basic question. In upholding the requirement to view and store the "original mammogram," how can a facility or vendor properly demonstrate that a "nonidentical original" as the result of data compression, for example, is in fact so functionally identical to the origin that it can replace the original? Of course, with regard to both printing of film and display and monitors, one must recognize that all existing systems slightly alter the original today since no two printers or monitors are exactly alike.

So if a provider or vendor can follow a quality process that insures that other data altering steps such as data compression functionally

and visually preserve the information in the original image, why provide any barrier to that process with regard to mammography in distinction to all other forms of medical imaging? Again, we will discuss this in greater detail in the afternoon.

CHAIR HENDRICKS: Any questions or comments from the panel or from the audience related to the written comments? At this time, all of these presentations are open for discussion from the panel or from the audience. Barring any comments, we'll move then to the next speaker. I welcome Lt. Commander Sean M. Boyd who is Chief of the Electronic Products Branch to the podium to give us a radiologic health update. Lt. Commander Boyd, welcome.

LT. COMMANDER BOYD: Thank you. I do have handouts. I'm Sean Boyd. I'm going to give you a brief overview of some work that we've been doing over the past year to reconceive FDA's radiological health program. We've been working the past ten or twelve months to do this, acknowledging that many of the public health problems and issues

that prompted the promulgation of the Radiation Control for Health and Safety Act in 1968 have changed although our public health mission today remains. So we have a fairly-detailed-but-in-process plan to address current public health problems for today.

What has changed since 1968? The three areas in your slides you'll see are first product environment. We believe that the markets have become global, not longer products just primarily made for the U.S. or in the U.S. market. Manufacturing processes have advanced, promoting safer building and testing and evaluation of products and more effective international voluntary standards are in place today; whereas, 25, 30 plus years ago, the standards that were in place were primarily FDA standards.

Public health needs have also changed where product problems or manufacturing problems were our primary concern in the late 1960s and early 1970s where today we believe that those problems either can be or already have been addressed for

many of the products that we began regulating years ago. And the issues today are more related to product use.

Finally, CDRH resources have changed where over the past few decades our focus has shifted more towards medical devices and our radiological staff and expertise has declined which primarily if you look at the FDA history on the next slide, the point of this slide is to say not that we don't have as many people as we used to, certainly we don't, but we need to be more cognizant of the resources, the few resources, that we have and best use those resources to deal with high priority problems, dose-intensive equipment and real public health risk.

Slide 5 shows the CDRH program mission; again, remains to protect the public from hazardous or unnecessary electronic emissions. The way we do that is by maintaining awareness of radiation-emitting products and their manufacturers, who is making what and what they're making, assessing radiation emission levels and conditions of use for

these products, understanding the effects of the emissions and their potential risk to health for the public, providing guidance to mitigate these risks both to the users, to the public and to manufacturers and encouraging manufacturers to comply with requirements or available standards while pursuing enforcement action when necessary.

Slide 6 shows our five program elements that we have developed in our Radiological Health Plan for the future. I'm going to focus on the top three today, standards, monitoring and education.

Slide 7 shows the goals for standards which are primarily using performance standards that are enforceable and appropriate for today's technology and these would be FDA performance standards that are required that manufacturers comply by law while increasing use and reliance on either international or national voluntary consensus standards. What we hope to do is establish processes that we are able to insure conformance with whichever of these two standards, a mandatory or consensus standard, by manufacturers when they're

appropriate.

Some of the activities on Slide 8 that we're hoping to cover and currently have in process with regard to standards are increasing our and other stakeholder participation and development of international and national consensus again focusing on high risk products and dose-intensive equipment by allowing conformance to consensus standards, by guidance which would be followed by adopting a standard by reference. We have done that with our Federal Laser Standard where we've adopted the IEC or we allow manufacturers to conform with the IEC Laser Standard by guidance and are moving to adopt that standard by reference. We are going to look into a similar paradigm for other standards to include the CT, ultrasound or other diagnostic x-ray standards.

Another thing that we hope to do or we're looking into right now is pursuing legislative change that would allow adoption and enforcement of voluntary consensus standards. This is not something that would be required or impact other

portions of the plan but if this is something that we could do to facilitate our use of approach consensus standards as necessary that might help us insure product safety. Finally, we want to base enforcement actions within the standards to lower risk.

Slide 9 shows goals for monitoring and the monitoring portion of our plan. Essentially, we'll want to maintain awareness of radiation-emitting electronic products and their manufacturers. We want to be able to assess electronic product emissions and their conditions of use. And we want to be able to understand the effect of emissions and exposure on risk.

Some of the activities on Slide 10 that we are pursuing and monitoring right now are to require only essential manufacturer reporting. We're going to relieve or provide some relief to manufacturers of low-risk products and not require as many or all the types of reports that we have in the past for low-risk products but maintaining the reporting requirements for higher risk, dose-

intensive equipment.

At the same time, we want to move away from routine field and lab test programs that we currently have and move toward more-cause testing, field and lab testing and primarily to manufacture inspections. One of the things you probably talked about is we're exploring elimination of the dose measurement during MQSA inspections. We're exploring phasing out routine laboratory and field testing again in favor of for-cause testing where we would be able to identify a specific problem or a manufacturer that would be of higher risk than another that might be covered in a routine program.

We're looking to phase out certain instrumentation calibration capabilities that we currently have in favor of maintaining instrumentation expertise and the capability to measure a variety of types of radiation from a variety of products.

And finally under monitoring, we want to work to emphasize assessment of use and exposures by harvesting data from organizations that are

currently collecting exposure and dose information rather than collecting that data ourselves. We may or may not have the resources to go out and collect all the type of data that we want, whereas other organizations are already collecting it. So if we can work together with people to collect that, that's what we would like to do.

Slide 11 shows our goals for education. We have a goal of having a public able to make informed choices about their own exposure in a variety of settings that might include medical, occupational or the home environment, a goal of having users able to minimize their own exposures and optimize the exposure and dose they're providing to the people they are treating or exposing. Manufacturers today are able to understand their responsibilities in educating the public and users and are sensitive to the risk their product poses and appropriate information or actions they need to take to minimize that risk as well as FDA and state regulators that assess users in minimizing radiation exposure to the public.

Some of the activities that we're pursuing right now under education include creating a coordinated education program where we're working to partner to disseminate information and create training opportunities with groups of organizations and primarily invest in the website as an educational tool. We're working right now to revise our web page to provide more timely and current information on radiation risk, the products we regulate both to consumers, users and manufacturers of the products that we regulate.

The benefits that we hope to reap from our efforts include aligning our efforts with today's current and evolving public health needs as opposed to what we have done over the past decades. We hope to expand our focus on patient and consumer needs while maintaining the oversight we have over the manufacturing community, targeting our regulation to dose-intensive equipment and where the true public health risks are, increasing the information that we provide to our stakeholders, manufacturers, users, regulators and the public and

improving coordination across the radiological health community.

That concludes my remarks. I've provided my contact information. There is information available on the CDRH web page on these new initiatives and you can get a copy of the plan there. There's also a public meeting that will happen on October 31th and November 1st. And there's a *Federal Register* notice that published recently on that as well.

CHAIR HENDRICKS: Thank you very much. Any questions or input from the panel or from the audience related to the presentation? I just do have a simple question for clarification regarding the devices that you were referring to as higher risk and I wanted to have a clarification for what those devices might be.

LT. COMMANDER BOYD: FDA regulates virtually any electronic product that emits any form of radiation. Television products and microwave oven products are two examples of products that we began regulating when the Radiation Control for

Health and Safety Act was promulgated decades ago. Those would be examples of low risk devices. CT scanner, radiation therapy equipment, primarily ionizing medical types of equipment are things that we view as highest priority for this.

CHAIR HENDRICKS: So all the medical applications are really considered high risk.

LT. COMMANDER BOYD: Right.

CHAIR HENDRICKS: Thank you. Okay. As we move along, we have two speakers who are going to speak jointly or split the time. We have Priscilla Butler from the American College of Radiology speaking first on providing an update on the Current Voluntary Interventional Mammography Accreditation Programs. Welcome.

MS. BUTLER: Thank you. I thought we were ready for the break but here I am. I'll be giving you a brief update on what's going on with stereotactic breast biopsy accreditation. Next slide, Mike, please. The Stereo Accreditation Program was first offered in 1996. It was modeled after the Mammo Accreditation Program which was very

successful even though voluntary at that time.

I do want to point out that the stereo program only evaluates breast biopsy procedures. There's no needle localization or ductography or other interventional procedures evaluated during this program and as with all of our accreditation programs, we look at personnel qualifications, clinical image quality, phantom image quality and dose, all of our x-ray programs look at dose, and the facility's quality control program.

Just like mammography, we evaluate personnel's initial qualifications. That includes their initial training as well as their initial experience, what they get during continuing education and continuing experience.

The physicians, we look at physicians, medical physicists and technologists. Back in 1996 with the realization that stereotactic breast biopsy was being performed not only by radiologists but also by other physicians. The ACR and the American College of Surgeons worked out and published a very detailed set of qualifications and they also defined

several settings which these physicians would practice in.

The collaborative setting is the setting where a radiologist and other physicians would work together in the same setting both performing stereotactic breast biopsy procedures but perhaps focusing on different aspects. But they would basically support each other in those efforts. And most accredited facilities that we look at tend to practice in an independent setting where the radiologist or the other physician would work independently or as a group from the other specialty.

I'm not going to go into the details of those requirements. I have provided a handout with those requirements if you want the other information.

With regards to clinical images, at this time we look at both masses and calcifications facilities must submit what they consider to a good example of a mass biopsy and a calcification biopsy. We evaluate needle devices, vacuum suction devices

and since there has been recently a number of FDA approved core biopsy devices such as M block, we've also started evaluating those.

The basic criteria for clinical image quality has to do with accurate needle positioning of the targeted lesion. So this is what our pass/fail criteria is based on.

For the phantom images and dose, first of all, dose must be less than 300 millirads and the phantom image quality criteria is going to vary depending on phantom is used. Just like mammography, we look at fibro specks and masses and there are two phantoms that we tell the facilities they can use. There is a mini phantom which has an abbreviated set of test objects which actually is good for defying gravity because it has a little lip that can hang off the devices and then they can also use the standard mammography accreditation phantom for the image quality evaluation. And we have separate procedures to use both of those tools.

We require that facilities perform quality control and the quality control that we ask

for are those tests which are outlined in the 1999 Stereo Breast Biopsy Quality Control Manual.

Our reviewers must essentially meet the same qualifications as the mammography accreditation program reviewers. The reviewers must be ABR certified and must be ACR members. They have to participate in a formal training program. They have to have a minimum of five years of experience and they must in current or clinical physics practice across the United States.

We are very careful to address potential conflict of interest issues. We have an automated system to remove them from evaluating any facilities which may be from the same state or any other state which they've identified a conflict of interest and we also perform quality control on the reviewers.

With that background, I would just like to show you some of our current data. This is a chart showing the volume of accredited facilities over time. Currently we accredit 436 units at 428 facilities. There are a couple facilities out there that do have multiple units. We've seen a slight

increase over the past year. We were getting worried from 2002 to 2004 because it looked like we were seeing a trend with facilities pulling out accreditation and there was less and less of an interest getting accredited. Recently we've seen an increase in accreditation. I'm not exactly sure what to attribute that to but we'll continue watching this.

The other thing I think is of interest is what our pass/fail rates are. And just like mammography accreditation, facilities have three attempts at accreditation. Basically, it's not a three strikes you're out but a three strikes we show up on your doorstep. And the first attempt at accreditation if they do not pass they get a deficiency.

Now what I'm showing you on this slide is first let's focus on the green bar. This is the overall pass rate after the first attempt at accreditation. In 2000, it looks we just had about 60 percent overall pass rate which means 40 percent of the facilities applying were not passing

accreditation.

We thought we were seeing an increase in the number of passing back in 2004 because we had almost reached 70 percent. With the data that I just ran last week, it looks like it's just dropped slightly. But I'm not sure because of these numbers how statistically significant they are for the year. But again, one thing that's really important to realize is in a very similar program and in fact in some sense more strict because of the MQSA regulations, mammography passes 90 percent of the units on their first attempt at accreditation now. In mammography when the program was still voluntary, we were seeing about a 70 percent pass rate. This pass rate hasn't changed significantly over the past four or five years.

Now the other thing that's interesting to note is the red and the blue bars. The red bars are the number of units, are the initial accreditation, which means that the unit goes through accreditation for the first time. Then the blue bars are renewal accreditation. We were seeing

again in 2003 and 2004 a significant improvement in the number of passes upon renewal which was really a good sign.

In 2005 again we need to look at this data carefully. I'm not exactly sure what has happened but one thing that we did see in the mammography program is as the program got out, many facilities were replacing their old units and all of a sudden, we started seeing the initial accreditation creep up in the pass rate because these initials were brand new units that these facilities were installing. They were higher quality. They were doing a better job.

Then some of the renewal, the pass rates started going down, because they were renewing with the same old units they've had for the past 15 years. So this is a trend that we have to watch to see if it's following what we've seen in mammography. But we will watch this.

Then the last piece of the pie that I want to present is that why are facilities failing accreditation. The vast majority are failing

because of clinical failures and we have 63 percent failing due to clinical only and another 10 percent failing due to clinical plus phantom. What this means is that the facility submitting their accreditation applications and they think it's their best work, our reviewers have determined that they have not been able to adequately target the lesion and that's why they're failing. So similar to the mammography, most of the deficiencies that they're getting are due to clinical reasons rather than a phantom or a dose issue.

I'll be happy to take any questions or we can wait until after our next speaker.

CHAIR HENDRICKS: I have a question just for clarification.

MS. BUTLER: Yes.

CHAIR HENDRICKS: Regarding the clinical process, are the facilities submitting the pre biopsy films and then the procedure related films and also the images that are obtained of the cores and then maybe some post procedure films? I'm not sure what the process is for the clinical review.

MS. BUTLER: Okay. The details of the process are in the handout that I gave you and in a nutshell, they submit the mammograms where they've identified the lesions they want to target and then they will submit pre biopsy images, post biopsy images and for calcs, they'll submit the specimen radiography exams.

CHAIR HENDRICKS: And the post procedure films if they are available?

MS. BUTLER: In terms of mammograms or as far as the biopsy?

CHAIR HENDRICKS: Yes, mammography.

MS. BUTLER: No, not the post procedure mammograms.

CHAIR HENDRICKS: So it's a question of whether the calcifications were present in the core specimens? Is that the critical question?

MS. BUTLER: They need to be able to see the calcifications on the original mammograms and then they need to be able to target those calcifications if it's a calc and then show on the core and that would be during the post biopsy exam

and then on the core be able to show that they got those calcifications on the specimen radiography exams.

CHAIR HENDRICKS: I understand. And during the accreditation procedure, for example, how many of these examples are submitted? This may be in the text but I just wanted to know how many samples are submitted to determine the pass or fail in the clinical. How many examples are submitted by the facility?

MS. BUTLER: We ask them to submit two cases, one showing an example of the accurate targeting for a mass and also one for calcifications. If they do FNAC, we also ask them to submit those cases too.

CHAIR HENDRICKS: So in order to receive a passing grade on the accreditation, then both of those sets need, in other words, confirmation procedure, if they fail on one, they receive a fail.

MS. BUTLER: That is correct. If they do not pass on one of those exams, if they receive a deficiency, then they don't get accredited.

CHAIR HENDRICKS: I see. Thank you.

MS. BUTLER: And one other thing I did forget to mention is we have a very similar program for breast biopsy accreditation and the criterion in a lot of ways is very similar.

CHAIR HENDRICKS: The facility is selecting the images that are submitted to ACR for accreditation.

MS. BUTLER: That is correct. We asked them to submit an example of their best work.

CHAIR HENDRICKS: So then are you surprised at these failure rates since the facilities have identified these two case as their best work?

MS. BUTLER: Yes.

CHAIR HENDRICKS: Then you point out that that's the same as mammography accreditation facilities, similar to the best work for people --

MS. BUTLER: Yes, in mammography accreditation, facilities are also asked to submit examples of their best work and I do need to point out that our reviewers know that they're evaluating

best work and they judge this accordingly.

CHAIR HENDRICKS: Thank you. Other questions or comments from the panel first for this speaker? Dr. Williams.

MEMBER WILLIAMS: I just missed your comment there, Penny, about you also have a program for what other kind of breast biopsy that are similar.

MS. BUTLER: Breast ultrasound.

MEMBER WILLIAMS: For ultrasound. Okay.

MS. BUTLER: For breast ultrasound and that evaluates not only breast ultrasound image quality for routine breast ultrasound imaging, but also breast ultrasound biopsy procedures.

EXEC. SECRETARY FINDER: Can I just have people hold for a minute so we can get Dr. Harrison back on hopefully.

(Pause.)

CHAIR HENDRICKS: I have another question for clarification regarding the numbers of the facilities so far that have participated in the voluntary program, two questions really. What

percentage of this volume is the total pie of the number of stereotactic equipment that we think we have in the United States right now, just a ballpark? What fraction?

MS. BUTLER: We estimate that there's about 3,000 units.

CHAIR HENDRICKS: Three thousand units. Okay. And the other questions in terms of the individuals in the facilities that have agreed to do this voluntary program, was it primarily academic centers or individuals radiology groups, surgeons? What is the mix of the individuals who agreed to participate in the voluntary program?

MS. BUTLER: In this program it's primarily radiologists and the practice setting really are all over the place, lots of academic centers. We also have a lot of community practices, smaller hospitals, that go through accreditation.

CHAIR HENDRICKS: So you felt like you got a reasonable mix.

MS. BUTLER: Yes.

CHAIR HENDRICKS: Although it's a fairly

small sample of what's going on out there?

MS. BUTLER: Yes.

CHAIR HENDRICKS: Thank you. Questions or comments from the panel first and then from the audience? We do have a question from the audience. Can you come to the microphone and reintroduce yourself for our speaker or our panel member at a distance?

MS. WAGNER: I'm Judy Wagner. I have a question just to clarify. The first bar is the initial. The second bar is the redo. And the third bar is the total of the two?

MS. BUTLER: Yes.

MS. WAGNER: And one other question, where you have for comparison over 90 percent of mammography units currently pass on the first attempt. So what really stands out to me, and clarify this if I'm wrong, is that mandating these things raises the bar for quality rather than it being voluntary. Would that be correct?

MS. BUTLER: Yes.

MS. WAGNER: Thank you.

MS. BUTLER: What we saw during the mammography accreditation program is after MQSA went into effect was a steady increase in the pass rate. What we also saw in mammography accreditation is that immediately after MQSA went into, just prior to MQSA going into effect, facilities that did not pass accreditation many of them dropped out and they didn't continue pursuing accreditation. After MQSA went into effect, that didn't happen any more because they didn't have that option. It may be applicable to stereotactic breast biopsy. There's a lot of similarities that we're seeing right now.

CHAIR HENDRICKS: A question from the panel.

MEMBER MONTICCIOLO: I just have a question for Ms. Butler. Penny, you said that it's mainly radiologists who have applied so far even though the practice settings vary. We don't really have a good handle on what non radiologists are doing from the numbers. Is that correct?

MS. BUTLER: We have several surgeon practices that have applied for accreditation and

the next speaker will be talking about the American College of Surgeons Program which we provide support for.

CHAIR HENDRICKS: Dr. Barr.

DR. BARR: Helen Barr, FDA. Penny, do you follow these submitted cases to look at what the diagnosis was? In other words, is there any correlation between failure? Does failure prove that the biopsy was not diagnostic? Is there any correlation between your failures and diagnosis of the lesion? Do we have any evidence on that?

MS. BUTLER: This is not something that we've been tracking and I guess I'm trying to figure out how we would do that. But no, I have no data on that.

CHAIR HENDRICKS: I just have another question for clarification regarding the process because we've been talking about how burdensome some of these processes are and that that might be a deterrent for voluntary participation in these programs. So in terms of the clinical component, what is the obligation to the facility? How much

time does it take in terms of preparation for this accreditation in your estimation? What is the burden to the facility to participate in this program in terms of manpower, fees?

MS. BUTLER: As far as fees go, it's $1,200 for the first unit and I believe it's $1,050 for the second unit. We don't have that many for second units out there.

As far as time goes, the documentation of personnel requirements is critical but most of the physicians, for example, and even the technologists, certainly when the medical physicists are involved, they are already in the habit of documenting this information because they're required to under MQSA and in fact, many of the personnel requirements really parallel what MQSA requires.

The quality control, there certainly is time associated with that and I don't have immediate figures on that right now. But once again, a lot of the tests are very similar to what's required for MQSA. An annual medical physicist survey is also

required. But all these things I think are good practices that have been established through MQSA and I wouldn't say that this is more burdensome than MQSA perhaps in some sense because it may be less burdensome, but just because MQSA has already taken a lot of the burden regarding the personnel stuff.

CHAIR HENDRICKS: Thank you very much. Dr. Monticciolo.

MEMBER MONTICCIOLO: This is Dr. Monticciolo. I would echo some of the things that Penny said like my site is accredited for a stereotactic. So I've been through this process and a lot of the things we would do anyway just for quality purposes, it's a good idea. We QA the machine every single morning so that we're ready and make sure everything is calibrated for every patient. So we would do that anyway. I think most of the requirements for the accreditation program are reasonable.

The only issue that we're having and is probably going to be addressed in committee and you could speak to this, Penny, is that it's currently

required that we submit images on masses and calcifications and almost all masses we see well with ultrasound. So we probably see them with ultrasound. The last time we went up for accreditation we had a hard time getting the mass because I didn't want to put somebody on the table just to get the accreditation when I knew it was easier for the patient to have an ultrasound if you're a reasonable clinician and you care about your patient.

People said to me, "Why don't you just put somebody on the table with a mass" and I couldn't just bring myself to do that. So it took me a long time to find a mass that we couldn't see with ultrasound and we could the stereo biopsy. That's probably something that's easily addressed.

MS. BUTLER: I'd like to comment on that. That's why I carefully chose my words when I talked about masses at this time. Dr. Phil Evans who is chair of the committee is actually convening a meeting to look at the mass issue and where we are at this point in time. Medicine evolves and I think

our programs have to evolve to appropriately reflect how we evaluate these medical procedures.

CHAIR HENDRICKS: Thank you. I just have one quick question just for clarification again. How were the participants identified to participate in this voluntary program? Were they new machine purchasers of new equipment or facilities who had already been involved in the MQSA inspections? How were the participants identified?

MS. BUTLER: Basically, they self-identified themselves. This is a study. This is an accreditation program and these facilities applied to us for accreditation in order to try to do demonstrate the quality of the work that they're doing there. As with all of our accreditation programs, they start this way.

CHAIR HENDRICKS: Thank you. I question from Dr. Williams and then from an audience participant.

MEMBER WILLIAMS: This is Mark Williams. Just in follow-up to the question about the burden just from the standpoint of the physicist, I don't

know if Melissa and the other physicists in the audience share this experience, but we found that the annual physics survey for the stereotactic systems actually takes less time than for a normal mammo unit. So the burden level there, I would say, is less even than a normal unit.

CHAIR HENDRICKS: Melissa.

MEMBER MARTIN: Melissa Martin. I would reiterate what Dr. Williams just said. Certainly the time on the machine for the physicist is definitely less than on a standard mammography system and I think there is a direct correlation with that. We have several facilities in a range of settings.

As a consulting physicist, we have very few academic centers. So ours are primarily community based hospitals and private offices. Several have voluntarily gone through the accreditation program and they do not find the QC for the stereotactic, that is, the least burdensome process that they have of all the breast imaging equipment in the department.

I would just also offer. We actually have several sites too that have voluntarily gotten the ACR manual for quality control, adopted that program and use it in-house even though they haven't paid the $1,200 to get accredited. But they want that QC program and that's what they use to document for quality control just within their own centers which I would find if that is a truly burdensome process, it wouldn't be done voluntarily in-house. So I would just reiterate. The QC part is not burdensome on that program.

CHAIR HENDRICKS: Thank you very much. Any other questions or comments from panel members?

MEMBER PASSETTI: Bill Passetti. You said there was about 3,000 facilities in the country, somewhere around that neighborhood.

MS. BUTLER: Yes.

MEMBER PASSETTI: Do we know how many of those are MQSA accredited facilities or totally separate?

MS. BUTLER: We have no data on that. I would imagine just from our anecdotal experience

that most stereo units are associated with an MQSA certified facility. So if it's a dedicated prone table, obviously it wouldn't require MQSA accreditation. There are some add-on units out there and most of these add-on units actually mammography. So they would have to be covered under MQSA.

CHAIR HENDRICKS: Yes. Carol Mount.

MEMBER MOUNT: I just wanted to echo the quality control program from the technologist standpoint is also very easy to do. The technologist in the breast imaging department are very familiar as Penny said with going through and doing the weekly QC and it takes minutes in the morning to get the machine ready and then they do their checklist and their quality control. So it's not a burden at all to the technologist to add this to their daily work.

CHAIR HENDRICKS: One final comment from the audience before we move on.

MS. WAGNER: Judy Wagner, R.N. I just want to tell you that in my presentation I get

questions from women all the time and the big question is where do I find in an accredited breast center. So I have now put it in my PowerPoint presentation. The ACR has a wonderful site. You go under ACR.org under Facilities and you can find if your sister lives in Missouri, you look up all. You look under stereotactic. You plug in stereotactic and you plug in the city. If you can't find that city, just use Missouri and all of the accredited centers for stereotactic will come up in that area. Same with ultrasound. So it's a really good resource. I have it in my handouts to women so that they can network this knowledge to other women.

MS. BUTLER: Thank you.

CHAIR HENDRICKS: Thank you very much and thank you for your presentation. We'll move then to the next speaker who is Kambiz Dowlat, Dr. Dowlat, welcome, to talk about interventional procedures related to breast disease.

DR. DOWLATSHAHI: Ladies and Gentlemen, thank you for inviting me to present the views of the College of Surgeons as well as myself regarding

the stereotactic programs. I was called in because I was involved with this device from the first day but I didn't have a lot of time to collect information and data. So my presentation is going to be very general and hopefully I will give you some message as to what we surgeons think about the stereotactic needle biopsy and it's safety and efficiently.

Some historical notes. This is a little bit of too much writing but I'll try to read it for you. Screening mammography as most of you may know started in the "60s with the Shapiro reporting in New York the data and subsequently on a wider scale around the country in the late "70s. Then it became very widely applied tests in the United States, I would say, in the late "80s and early "90s.

The suspicious lesions that were detected by mammography were wire localized by radiologists and removed by surgeons for diagnosis. This is where I was involved with the mammography and this is how I became more interested in breast cancer detection and diagnosis and treatment.

As I said, I introduced the stereotactic needle biopsy in the United States from Sweden only because I did not think that wire localization and excision was a good way of doing things because 75 to 80 percent of the biopsies that we did at the time were all benign. I thought that was unfair to women.

So the technique was developed in Sweden and the first unit was brought into the University of Chicago and that's where I worked with it and tested it against the open biopsy and others have done equally well and subsequently this was accepted by radiologists at first because I couldn't sell it to surgeons and then the surgeons came into the field at a later stage.

Breast ultrasound was also a diagnostic step for intervention. It was popularized by my colleague, Dr. Staren, at Rush in Chicago. This was again a historical note which I want to introduce because both the stereotactic and ultrasound came together in the mid "90s when the need for intervention became obvious.

In 1997, the surgeons felt somewhat threatened that their practice was taken over by intervention or radiologists and they went to the College of Surgeons and they asked me and Dr. Staren and we formed a group and started the stereotactic and ultrasound courses given at the College meetings twice a year.

In the earlier phases of these courses, we were giving certificates to the participating individuals so that they could go back to their hospitals and start practicing the intervention of steps being either stereotactic or ultrasound.

A set of guidelines as was pointed out by the previous speaker was developed in conjunction with the College of Radiology and I have a copy of that for the panel. Unfortunately, as I said, I didn't have enough time to make a lot of copies, but it describes what this voluntary program which is place by the College of Surgeons for their fellows and for their practicing fellows is all about.

My comment is that the practice of surgery is becoming more and more image dependent.

And you can see that if you go into any set of operating rooms in the hospital that something like eight out of ten surgeons are operating on the screen. Laparoscopic cholecystectomy is a good example as most of you know in the arthroscopic procedures and so on and so on.

The 21st century practice of surgery has become very image dependent. Therefore, surgeons have to become cognizant of what the mammographic problems are and therefore become familiar and become skilled at reading and intervening whenever is necessary.

Of course, safety of the patient and accuracy of the procedure through correct diagnosis is paramount. If you miss a cancer overdue or over practice the needle biopsy at the slightest risk of malignancy, it's a very fine skill and find experience to obtain. It takes time to be able to do this procedure both with ultrasound and the stereotactic.

Now image-guided treatment of breast cancer is also on the horizon. I'm sure a lot of

you know about the laser treatment of these tumors as well as the radio frequency, cryosurgery. These are all minimally invasive means of treating but image dependent methods of treating breast cancers. Surgeons are also involved with the placement of the radiation devices for partial treatment of breast tumors. So as I said, earlier on, more and more image dependent technology is coming into the field and we just have to learn about them.

In my opinion, the current stereotactic biopsy program as I have given copies to the panel members is adequate for practicing surgeons and should serve the primary goals of patient safety and the diagnosis of cancer. It's not popular with surgeons and radiologists for a variety of reasons. It adds a little bit more to their busy schedule. You just have to submit, I'm just saying that by having spoken to several surgeons in the past week, that if they are working with radiologists, life is made easier for them because the mechanism is already in existence for the submission of the application.

But if they are independent, they have to come up with the resources in order to fulfill the requirements and I think that's one of the questions that was brought up earlier on does everyone fulfill these requirements or participate in these voluntary programs or not. I'm trying to explain one of the reasons why it has not been followed through by a lot of surgical practitioners as independent practitioners.

I personally believe that the problem of dealing with breast disease and breast abnormalities should be addressed by the Residency Review Committee. This is a committee which reviews the material taught to the surgical residents. I think image guided breast biopsy and therapy should become part of the resident training program.

What we are dealing with now is insure that today's practicing surgeons are familiar and they practice correctly and they know how to handle biopsy or how to read the mammogram and so on. I think for the future this should be addressed at a much earlier stage of training of the surgeons.

You should be taught at the residency level at the major teaching hospitals. They all should have image guided training programs. This is a rapidly evolving field for which the trainees should be given instructions and then subsequently the American Board of Surgery should test them in order to assure that they are qualified for practice in this field.

That's my last one. I addressed the subject in a very general way but I would be happy to answer any specific questions to the best of my ability.

CHAIR HENDRICKS: Yes. From the panel first. Dr. Williams.

MEMBER WILLIAMS: This is Mark Williams. This is actually a question for either of the last two speakers. I was wondering. The ACR was obviously involved in putting together this accreditation program for the ACS. Could either of you just say in a couple of sentences what the major differences are between the two in terms of either the accreditation application process or in the

quality control procedures recommended?

DR. DOWLATSHAHI: As far as I know, there isn't a whole lot of difference. The brochure that I gave you I was involved with this development about four or five years ago and then it was recently revised. But it was developed jointly with the College of Radiologists. Would you like to add to that?

MS. BUTLER: Penny Butler, American College of Radiology. The requirements of the program are exactly the same between the American College of Surgeons' program and the American College of Radiology's program. The really only difference is administrative. The initial contact is made through the American College of Surgeons' Office but the review is done by the American College of Radiology reviewers for the American College of Surgeons program and then the results letter obviously goes to the facility from the American College of Surgeons.

CHAIR HENDRICKS: I have a question for clarification, Penny, please regarding the

applications. Have they all been under the collaborative track or have some facilities, some physicians, applied and been accredited on the independent setting track?

MS. BUTLER: In the American College of Radiology program, I would say most of the applications come under the independent setting track and because mostly radiologists are attracted to the ACR program, most of those would be radiologists. Although we do have some surgeons apply to our program and they'll also apply to the American College of Surgeons.

CHAIR HENDRICKS: I do note in reviewing the document that there do seem to be some differences related to the quality assurance activities. This is in response to Dr. Barr's comment about following up the number, some audits details, of biopsies, cancers, followed, biopsies needing repeat biopsies and then the false negative and PPV values in the practice. So is there some of that data that is being generated now as part of the current accreditation process for the physicians on

the independent track?

MS. BUTLER: Unfortunately at this time, we are requesting this audit data but it's not a requirement that they do it and I think I have that in here. But we're trying to get that data. I don't have that data analyzed in order to present.

But another thing I did want to point out to Dr. Barr's question, of course you only think of these after you sit down, is regarding the diagnosis and correlation we don't have that for mammography either.

CHAIR HENDRICKS: Thank you. I have one other question for both of you related to how the surgeons who participate in the collaborative setting track to meet these accreditation criteria, how they document that they have read the 480 mammograms in conjunction with a radiologist or independently with separate, I don't know what the language is, for confirmation of their mammography requirement to be accredited?

DR. DOWLATSHAHI: I think if I just answer that question with the focus on surgeons who

more than 50 percent of their practice is breast surgery. They see easily, myself I see, more than 20 patients a week and that comes up to 1,000. I think that's because 95 percent of my practice is breast surgery. But for those who are even 50 percent of their practice is breast they easily see 480 mammograms either independently or in conjunction with a radiologist.

CHAIR HENDRICKS: So is that an assumption that those physicians met that criteria based on this descriptor or is there someway to quantitate the matter?

DR. DOWLATSHAHI: Do they actually write it down on a daily or weekly basis? I think some do but not all.

CHAIR HENDRICKS: So it's not a requirement at this point in time to demonstrate that the physicians on the collaborative setting track the mammograms.

DR. DOWLATSHAHI: That's part of the requirements. It's part of the requirements that they should read or interpret that many mammograms

every year in order to remain on the ball.

CHAIR HENDRICKS: Thank you. Yes, Penny.

MS. BUTLER: Penny Butler, ACR. From the American College of Radiology perspective just to differentiate, the American College of Surgeons evaluate the personnel qualifications and the ACR evaluates the personnel qualifications for facilities accrediting through us. We require them to sign an attestation that they have met these qualifications and then when we do site visits, we notify them that they must agree to a site visit at any time. When we do our site visits, one of the things that we look for is a log for whatever setting they're in that they actually have that documentation in place.

CHAIR HENDRICKS: Thank you very much. Other questions or comments from the panel or from the audience? Yes, Carol.

MEMBER MOUNT: I have a question for both of you or either one. What happens when you have a facility where the radiology department has

an accredited biopsy table and the radiologist and their team is accredited. The surgeon also wishes to use that table and they are not accredited? What happens or does it work?

DR. DOWLATSHAHI: This is Dowlat from Chicago. I think the surgeon usually has taken the training course either by the College of Surgeons or by another accredited organization and is familiar with this procedure. Therefore he may not have that document from the College of Surgeons yet if that is what you are talking about.

MEMBER MOUNT: Right. I'm just wondering. Is it then legal for him to use this machine that is accredited?

DR. DOWLATSHAHI: Is it legal?

MEMBER MOUNT: If it were a mandated process, would it be?

DR. DOWLATSHAHI: I think that would be yes. But at this point because it's a voluntary program the onus is on the surgeon to have taken the course and to have passed the test because also taking the course, they are given a test to insure

that they have understood and they know how the machinery works before they go to the site. When they go to the site, they usually are supervised in the first cases either by another surgeon or by a radiologist.

MS. BUTLER: Penny Butler, American College of Radiology. In the ACR program, I would hope that scenario would be covered under a collaborative setting and that the surgeon would be working with a radiologist in that setting and would have the appropriate documentation available to show that the individual is qualified.

Unfortunately, that's not always the case and the accreditation has been applied for by a radiologist. One thing that we have in our survey agreement with all of our voluntary accreditation participants is that all personnel that work in the procedure must be qualified and that the lead interpreting physician there is responsible to making sure that all personnel meet the qualifications. If the qualifications can't be documented that they've been met, the American

College of Radiology would have to look at as to whether their accreditation could be maintained.

CHAIR HENDRICKS: Thank you very much. Any other questions or comments from the panel? Yes, Dr. Ferguson.

MEMBER FERGUSON: Does the American College of Surgeons believe that accreditation should be mandatory?

DR. DOWLATSHAHI: Not being directly in the College myself, I think the answer is that at this time they think if the voluntary system works they should keep it as such. This very question was actually debated several years ago when I was intimating involved with this program and it was tabled. I don't know what is the official view of the college at this time.

MEMBER FERGUSON: Your personal view.

DR. DOWLATSHAHI: My personal view is that this is a kind of a skill that a surgeon should have. If he or she is going to treat a patient for diagnosis or treatment, it makes no difference whether it is an imaging program related to breast

or to the heart or liver or gall bladder or something. He and she should have that skill. It's the same as a biopsy, introduce that instead of full dissection. Thirty patients are a minimum number of cases done before the surgeon knows that he or she is adequately skilled to operate on their own.

The same thing is here. I think they should know enough to be comfortable and secure that they do a good job and they fulfill the criteria for QA and QC.

MEMBER SEGELKEN: Jane Segelken. I just have a comment about that and in a rural community for example where I'm from, there are only 20 people a year even diagnosed with breast cancer. So when you're talking about such a small number of people to have that kind of experience may or may not happen. So at least you'll have an important comment to make.

CHAIR HENDRICKS: The access question. Do you want to respond to her before we move to the next comment from a panel member?

DR. DOWLATSHAHI: Sure. You want me to

respond to that. I think a small community is when 20 breast cancers are diagnosed a year. It may unfair for a surgeon or radiologist to go into the trouble of learning this procedure and to become quite skilled at it. I think it may be better if the people from the small community went to a larger community near by. I don't know the geographic location of your center, but I think it would be to the advantage of the patient to travel maybe 50 miles to a larger center where the surgeons and radiologists are very accustomed to this technology.

CHAIR HENDRICKS: Thank you. Another comment from the panel?

MEMBER MARTIN: Melissa Martin. A question and maybe I missed it. You're both talking about programs. We've heard numbers about 3,000 units available. We saw numbers around 475 are currently voluntarily accredited. Do you have a breakdown of how many are accredited through the ACS program and how many of those 475 or so through the ACR program are the standalone surgical centers?

DR. DOWLATSHAHI: I think most of the

numbers that given to you are by the ACR. Very few are through the ACS.

MS. BUTLER: Penny Butler, American College of Surgeons. (Laughter.) Let me take that back.

DR. DOWLATSHAHI: Now that you brainwash her.

MS. BUTLER: Currently with the American College of Radiology. Currently we have in our records I believe it's 12 facilities accredited through the American College of Surgeons. I don't have a precise number for the number of independent surgical practices that are accredited through the American College of Radiology. It's not a large number though.

CHAIR HENDRICKS: Carolyn Hendricks, just a follow-up. What steps can ACR take and ACS take to increase the proportion of centers that participate in the program if we want to continue along the voluntary pathway?

MS. BUTLER: We have been trying. For all of our voluntary accreditation programs, we've

embarked on a marketing effort to raise the visibility of these programs. There has been some success working through third party payers who are obviously very much interested in scorecards and paper performance and everything else and some of them have become more interested. But I think if you look at the tracking of the number of facilities that have achieved accreditation since 2000 it doesn't appear that this has made a significant difference.

CHAIR HENDRICKS: Thank you. Maybe we'll take one more comment before our break. Welcome.

MS. WILCOX: In terms of the third party payer --

CHAIR HENDRICKS: Please introduce yourself.

MS. WILCOX: I'm sorry. Pam Wilcox, American College of Radiology.

CHAIR HENDRICKS: Thank you.

MS. WILCOX: In terms of third party payers, the ACR has been heavily marketing our

accreditation programs to payers as a way to improve quality. And unfortunately, although my soapbox is frequently to talk about stereotactic breast biopsy and breast ultrasound and the deficiency rates that we see there, they're really not interested because they're not high ticket enough items. They're much more interested in MR, CT and PET. So it is highly unlikely from my experience that the payers are going to look at making these programs mandatory. Thank you.

CHAIR HENDRICKS: Thank you. Yes, one comment. Diane.

MEMBER RINELLA: Just one quick final question. Diane Rinella. Of these facilities that are accredited with the ACS, these stereotactic tables, then that facility that is ACS certified does not have to have onsite a radiologist. Is that correct? So then the surgeon is going to be looking at films that the patient has brought in, assessing those films and then targeting the area themselves.

DR. DOWLATSHAHI: That's correct.

MEMBER RINELLA: Okay. Thank you.

MS. SPRINKLE: I just have one comment.

CHAIR HENDRICKS: Please introduce yourself at the mike first.

MS. SPRINKLE: Yes. Susan Sprinkle, mammographer, mammography technologist and consultant with Advanced Health Education Center in Houston. I just have a comment. Since Diane brought that up, it's the perfect time. It is also if you are not accredited, if your stereotactic program is not accredited, through the American College of Radiology, you do not have to have a qualified mammographer doing the procedure with the radiologist or the surgeon. We have gotten request at my company to train RTs to do stereotactic procedures and we have issues with that. We believe that a technologist that is assisting a radiologist or a surgeon in a stereotactic procedure should be a qualified mammographer.

CHAIR HENDRICKS: Thank you for that comment and with that we'll take a 15 minute break. Off the record.

(Whereupon, the foregoing matter went

off the record at 10:48 a.m. and went back on the record at 11:03 a.m.)

CHAIR HENDRICKS: On the record. I'd like to reconvene the meeting and ask the panel members in the audience to take their seats. Again just as housekeeping item, we want to ask all the speakers at the podium to state their names clearly so that it can be incorporated in the transcript of the meeting and so that our panel member at a distance can hear all the comments. We would like to keep the noise in the audience at a minimum so the participants and the panel members can hear the speakers.

With that, we'd like to welcome our speaker to the podium, Donald Flater who is Chief of the Iowa Bureau of Radiologic Health. Welcome.

MR. FLATER: Good morning. I want to make something perfectly clear and that is in Iowa stereotactic accreditation and certification is mandatory.

I'd like to first start out by giving you a little bit of information about the State of

Iowa and our program. We only have 2.8 million people in the whole State of Iowa. We have 138 hospitals. Of that, 96 of the hospitals are below 50 beds and probably half of that number are below 20 beds. So we don't have a lot of big ones. We have one large one or we think it's large and that's a 1,200 bed and that of course is the University of Iowa Hospital. We currently have 156 mammography units in the State of Iowa plus we have two digital units. That does not include the count on the stereotactics.

Now I'll refer to the handout that you have. Stereotactic units in Iowa, we have 24 which of that 24 there are two units that are mobile and there are three units that are upright. The rest of them are the supplying type units. Currently we have 85 radiologists in 22 facilities and physicians that are not radiologists, we have 24 that are in six facilities. Two of those facilities are solely surgeon facilities. They have no connection to radiologists. And four of those facilities have both radiologists and surgeons that use the

stereotactic units.

Listed below, the information on the physicians, are the noncompliance issues that we've had so far in 2005 relative to our regulatory program. We inspect each and every mammography unit and stereotactic unit annually and the reason we do that is the Iowa Administrative Code mandates that we have no choice but to do that.

You can see listed there the different types of noncompliances that we have found and I would call your attention to Items 7, 8 and 9. Seven, 8 and 9 all refer to one facility. The reason for Item No. 7 being there is that this whole process on these units happens to be a fraud issue where an individual fraudulently manufactured the phantom pictures. She did this on 11 different times that we know of. The reason that No. 7 is there is our attorney believes that in doing this she definitely jeopardized the public health and safety relative to patients that are going through stereotactics.

This individual has in fact gone to

court and we are waiting the final decision of the judge. What we have asked is that her certificate to practice mammography be revoked which basically means that it never could come back into effect. This happens to be an individual that has 26 years of experience at the facility where she did in fact the fraudulent activity and she does have about four years in another place. So she has 30 years of experience. We also found the same type of fraudulent activity in the regular mammography program.

You can see the rest of the information that's down there, the different ways that physicians can become qualified. Also attached there are the rules do specifically address the stereotactic processes and on the bottom of it you will notice the note the Iowa Administrative Code.

You have to be a little careful in Iowa. We talk about things like Iowa Code and Iowa Administrative Code. Iowa Code is law. Iowa Administrative Codes are rules. I give you this information and if you'll note that on page 42 of

the document is where the actual stereotactic information can be found.

We change rules on a routine of about once a year. As things change, we change rules as they're necessary. So it's a process we don't worry about. We're not like some places that take a long time to get rules through. Our maximum amount of time for a rule is from the time it becomes a notice, about five months, and it's in place. So we don't have a long period of time.

I would say that the program has worked well. We started back in the mid "90s. We have not had a lot of complaints at least that have come to my office. We did have some difficulties with the surgeons at first because they had never been through such a program or such a process. So they did have some trouble meeting some of the requirements. We've kept the same requirements ever since we started and in most cases, they have met them.

We did have a bit of a problem with some of the physicists inspections and that getting them

done in a timely fashion and that kind of thing. But that will all straight out. It's just a matter of bringing it to their attention and asking them to get it.

So it's been a good process. We do enjoy it. Of course, this is one where we do not have oversight from the FDA, but we're more than willing to share our information with them and we do talk with Dr. Finder every once and a while about issues that come up.

One other point that we are in fact trying to deal with at this point in time is the radiologist assistants. In this area, we have received a request from a training program that they be allowed to provide training to the radiology assistants.

Where our concern comes in is I know in the information that has been put out it says that they won't do any interpretation. That may be true in your setting that is not rural. But we have a number of facilities in Iowa where the radiologist is located at another hospital. The radiology

assistant come in. They do their work and then they take all that information back to the hospital and at times, they do make interpretations.

So I can see this program going the one step further and running into that issue. I'm not too sure it's not going to go that same way on our regular mammography program. I think those requests are going to come in as we have the continued problem with people and the number of people going into the practices and that kind of thing especially in the rural communities. We have one radiologist that covers seven different facilities. He likes to fly. So he flies from one to the next one to the next one. But we still run into some problems there.

So we're going to have to deal with that issue. We do approve schools and that kind of thing. So I'm sure we're going to get into the middle of that.

Again as I said, the rules are there. They're very specific. We do mandate and this is where we try to plagiarize quite bit on the ACR. We

do use their quality control information and we do mandate those kind of things. That's all I have unless I can answer some questions for your folks.

CHAIR HENDRICKS: Dr. Williams.

MEMBER WILLIAMS: This is Mark Williams. I just have one little question. You plagiarize the quality control from the ACR, but I notice that you didn't, unless I'm just overlooking it, include assessment of the collimation which actually can be a fairly important thing in stereotactic biopsy. Was that on purpose?

MR. FLATER: It probably wasn't on purpose. I didn't realize it was an issue but we certainly can take it up and we'll take it back and find out what's the problem. We do use physicists in fact in Iowa. In order to be a physicist on list you have to be either board certified or board eligible, one of the two. And that has never come up as an issue.

One of the noncompliance problems that we have had, you'll notice that No. 1 is they're not following the recommendation of or the indication

from the physicist which we go back and force them to do once we find out they haven't followed that. So the collimation issue may be addressed at that point in time. If the physicist says there's a collimation problem, they're going to have to fix it.

MEMBER WILLIAMS: Okay. I just didn't see it in your list. So I don't know if the physicist is looking at it or not.

MR. FLATER: I certainly will check on it.

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. Just for clarification, does your program have the same clinical component as the ACR program and, if so, what are the details related to the image review?

MR. FLATER: The image review, we require that they do provide images. The images go in front of what we call our clinical image review group. We have seven radiologists under contract. We provided the funding for them to all be trained as individuals that do stereotactics. We had that

done at the University of Iowa and then they are required to meet the same requirements as we have here. Even though they don't necessarily have stereotactic at their facility, they have to meet the same requirements in order to be an interpreting physician.

CHAIR HENDRICKS: Did you employ similar criteria for pass and fail and, if so, what kind of data do you have on your facilities at this point in time regarding pass rates and failure rates?

MR. FLATER: I can't answer that question because I'm not the one that takes care of that part of it. I listened to what Penny had to say and I'm certainly going to go back and ask our folks exactly what criteria they do use for the actual image review process.

CHAIR HENDRICKS: Yes. Dr. Barr from the audience.

DR. BARR: Helen Barr, FDA. Mr. Flater, do you have any evidence that with your mandatory program that there has been either an increase in capture of lesions during stereotactic biopsy or a